Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

March 24, 2004
12:45 p.m.

Attendees: Richard Freeman, Chair; Rob Colburn, Gary Magouirk, Ben Main, Jefferson Underwood, John Searcy, Louise Jones, Robert Berringer

Absent: Jackie Feldman, A.Z. Holloway, David Herrick, Melanie Smith

(1) Opening Remarks
Richard Freeman called meeting to order and asked that all cell phones and pagers be placed in the off position.

(2) Minutes from December 10, 2003 meeting were approved, motion was extended by Richard Freeman and seconded by Jefferson Underwood.

(3) Pharmacy Program update was provided by Louise Jones:

Ms. Jones announced that the Pharmacy Clinical Support contract had been awarded to Heritage Information Systems, Inc. Heritage will be responsible for presenting pharmacotherapy reviews to the Medicaid Pharmacy and Therapeutics Committee.

The presentation time for pharmaceutical manufacturers during the Pharmacy and Therapeutics Committee meetings has been changed from five minutes to three minutes. Presenters will hear a bell with one minute remaining and will be disallowed from speaking after the three-minute allotment.

Medicaid implemented a therapeutic duplication edit on February 19, 2004. The hard edit will block claims at the point of sale if medications are considered to be therapeutically equivalent. Some concern has been raised about drugs with the same name but with different strength being blocked from adjudication. As a result, the Agency is working with EDS to allow claims to be paid if the therapeutic duplication has same name different suffix. This application should be effective within one week.

Medicaid will begin to update ePocrates monthly rather than quarterly.

Maximum quantity limits for the erectile dysfunction medications have been changed. Medicaid will only pay for one tablet per month rather than previous amount of four per month.

Medications requiring prior authorization through the PDL have been updated on the Agency's website including those drugs for the treatment of ADHD. The website continues to be updated with new criteria and providers should continue to refer to the web for education about these changes. Health Information Designs, Inc. (HID) will continue to respond to criteria changes and lists of drugs implemented via the prior authorization process. Effective April 1, 2004 Medicaid will implement antihypertensives into the Preferred Drug List.

Volume discounts and supplemental drug rebate proposals from manufacturers will be accepted and evaluated at any time of the year regardless of when the class is reviewed.

The Agency is currently evaluating a script limit such as a four-brand limit and will be making a decision on this in the near future.

The Agency requests that all attendees to the Pharmacy and Therapeutics Meeting sign in before entering the auditorium for recording purposes even if that individual is not presenting during the meeting.

For clarification purposes, the Agency has added "new" next to those items that are newly furnished on the website and "updated" next to those items that have been refreshed. The webmaster is updating the website to reflect date of updates in the near future.

Ben Main requested an update on the cost savings initiatives per the meeting on December 10, 2003. Louise Jones responded that HID and the Agency had met the morning before the meeting and the summary report had not been fully evaluated, however there had not been a spike in the medical claims affiliated with the drop in prescription claims as a result of the data analysis by HID. HID and the Agency will work toward finalizing the report and presenting the other medical costs realized at the next meeting.

(4) Oral Presentations by Manufacturers/Manufacturer's Representatives for drug class reviews began at 1:15 p.m. Three-minute verbal presentations were made on the following drugs by, or on behalf of, the following Pharmaceutical Manufacturers:

Section I. Selected Serotonin 5-HT1 Receptor Agonists/Triptan Agents

Pharmaceutical Company	Product
GlaxoSmithKline	Imitrex
Pfizer	Relpax
Merck	Maxalt and Maxalt MLT

Section II. Selected Estrogen Replacement Agents

Pharmaceutical Company	Product
Dr. Tripp	All Transdermal Estrogen
Wyeth	Prempro, Premarin, Premphase

Section III. Selected Anti-inflammatory, Intranasal Corticosteroid Agents

Pharmaceutical Company	Product
GlaxoSmithKline	Flonase

Section IV. Selected Respiratory Agents

Pharmaceutical Company	Product
Dey Labs	AccuNeb and DuoNeb
AstraZeneca	Pulmicort, Pulmicort Respules, Rhinocort Aqua
Merck	Singulair
Sepracor	Xopenex
GlaxoSmithKline	Advair

Section V. Selected Antiarrhythmic Agents

No Oral Presentations by Manufacturers/Manufacturer's representatives for Section V Review.

(5) PHARMACOTHERAPY REVIEWS: Presented by Robert Berringer of Heritage Information Systems, Inc. began at 1:50 p.m. Robert Berringer thanked the Agency for the opportunity to be a part of the Pharmacy and Therapeutics Committee and the Manufacturers for their comments. (Refer to the web for full text reviews.)

Section I. Selected Serotonin 5-HT1 Receptor Agonists/Triptan Agents (AHFS Class 289200)

Robert Berringer stated there are seven agents within this class, all of which are relatively well tolerated and effective for migraine headaches. The major difference in the agents being pharmacokinetics which may affect such parameters as onset and duration of pain relief. All brand products within the class are comparable to each other and offer no significant clinical advantage over one another in general use. No brand triptan was recommended for preferred status.

After discussion amongst the board concerning the recommended status, Gary Magouirk moved that at least one brand Triptan be recommended for preferred status including different dosage forms. John Searcy and Louise Jones commented to clarify the Board's motion and the motion was seconded. Richard

Freeman responded the motion to amend the ballot as a separate choice had been noted and the Board members should add this choice to their respective ballots.

Richard Freeman then asked the Board to mark their ballots.

Richard Freeman initiated a break at 2 p.m., which lasted until 2:17 p.m.

Section II. Selected Estrogen Replacement Agents (AHFS Class 681604)

Robert Berringer stated the drug class reviews focused on both the single entity agents and the combination products. For the single entity agents, the Well-HART study was one of the best that looked at outcomes in postmenopausal women for the progression of coronary heart disease and women. All brand estrogen single entity products are comparable to each other and to the generics and offer no significant clinical advantage over other alternatives in general use. No brand single entity estrogen product was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer stated no brand single entity estrogen product is recommended for preferred status. Concerning the combination products, all are comparable to each other and to the generics and offer no significant clinical advantage over other alternatives in general use. No brand combination estrogen product was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Section III. Selected Anti-inflammatory, Intranasal Corticosteroid Agents (AHFS Class 520800)

Robert Berringer described the use of intranasal corticosteroids and six agents currently available as well as the treatment of allergic rhinitis in general. Two issues that Robert Berringer discussed included the adverse drug events due to Nasalide. All brand products within the class reviewed are comparable to each other and the generics in this class and offer no significant clinical advantage and Nasalide possesses an extensive side effect profile. Vote 1: No brand intranasal corticosteroid was recommended for preferred status. Vote 2: Nasalide should not be placed in preferred status regardless of cost due to adverse drug events.

Richard Freeman asked the Board to mark their ballots for each vote.

Section IV. Selected Respiratory Agents (AHFS Classes 120808, 680400, 861600, 121200, 920000)

Robert Berringer first spoke about the antimuscarinic antispasmodic agents as a subclass as alternative therapy for patients who do not tolerate beta-agonist

therapy. It was also discussed in general use. MDI therapy is considered first line versus nebulized treatments. In general use, the ipratroprium MDI dosage formulation is recommended over the nebulized treatment and is only available in brand formulation; brand ipratropium offers a significant clinical advantage in general use over the other brand and generics. Brand ipratropium was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the corticosteroid inhalers as a subclass and the five agents that are currently available. Robert Berringer stated that no inhaled corticosteroid is recommended over another and all brand products within the class are comparable. No brand-inhaled corticosteroid was recommended for preferred status.

Gary Magouirk motioned that at least one brand product be preferred and the motion was seconded.

Richard Freeman asked to note the recommendations and asked the Board to mark their ballots.

Robert Berringer discussed the single entity smooth muscle relaxants as a subclass and stated that all brand products within the smooth muscle relaxant class are comparable to each other and to generics in this class and offer no significant clinical advantage over other alternatives in general use. No brand smooth muscle relaxant single entity product was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the combination smooth muscle relaxants as a subclass and stated that there are no clinical head to head trails comparing indications, pharamcokinetics, drug interactions, adverse drug events, and dosing or administration. All brand products within the smooth muscle relaxant combination class are comparable to each other and to generics in this class and offer no significant clinical advantage over other alternatives in general use. No brand smooth muscle relaxant combination product was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the single entity sympathomimetic agents as a subclass and stated that long-acting sympathomimetics offer a unique clinical advantage over other sympathomimetics. Brand versions of formoterol (Foradil) and salmeterol (Serevent) offer significant clinical advantage in general use over the other brands in the same class but are comparable to each other. Medicaid

should work with manufacturers of the recommended brands of Foradil and Serevent on cost proposals so that at least one of the recommended brands is selected as a preferred agent.

Jefferson Underwood questioned the safety of Serevent used as mono-therapy based on guidelines presented to him. Robert Berringer commented that while the Serevent package labeling includes a warning that the Salmeterol Multi-center Asthma Research Trial (SMART) showed a small but significant increase in asthma-related deaths in patients receiving salmeterol versus those on placebo, it is unknown whether this is a class effect or isolated only to Serevent. Jefferson Underwood asked that the Agency take the safety factor into consideration if only approving Serevent as the only brand within this class.

Richard Freeman asked that the Board mark their ballots.

Robert Berringer discussed the sympathomimetic combination products and stated that while combination therapy has been shown to improve outcomes in patients with asthma or COPD, there is no data to support a combination product superior to using separate therapies concurrently. All brand products within the sympathomimetic combination class reviewed are comparable to each other and generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand sympathomimetic combination product was recommended for preferred status.

Richard Freeman commented on the Advair delivery package as more beneficial to the individual components. Robert Berringer stated no finding of this issue in the studies and in the Advair package labeling.

Richard Freeman asked Board to mark their ballots.

Robert Berringer discussed the leukotriene modifiers as a subclass and stated that all agents are comparable and offer no significant clinical advantage over each other. All brand products within the leukotriene modifier class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand leukotriene modifier product was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the mast cell stabilizers as a subclass and stated that no brand mast cell stabilizer is recommended for preferred status. All brand products within this class are comparable to each other and to generics in this class and offer no significant clinical advantage over other alternatives in general use.

Richard Freeman asked the Board to mark their ballots.

Section V. Selected Anti-arrhythmic Agents (AHFS Classes 240404, 240408, 241208)

Robert Berringer discussed the anti-arrhythmics as a subclass and stated that all products are comparable to each other and to generic products within the class and offer no significant clinical advantage over other alternatives in general use. No brand anti-arrhythmic was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the cardiotonics as a subclass and stated that ample evidence supports the use of digoxin particularly in Class II and III heart failure. Considering minor differences with respective pharmacokinetic parameters, all digoxin products are equally effective. All brand products are comparable to each other and to the generics in this class and offer no significant clinical advantage over other alternatives in general use. No brand cardiotonic was recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Robert Berringer discussed the nitrates/nitrites as a subclass and stated that overwhelming evidence supports nitrates' beneficial effects for the management of chronic stable angina and acute angina attacks. Since nitrates have the same pharmacological effects, they can be generally interchanged with appropriate dosing adjustment depending on desired onset and duration. All brand products are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand nitrate/nitrite products were recommended for preferred status.

Richard Freeman asked the Board to mark their ballots.

Louise Jones asked that ipratroprium replace the brand name Atrovent on page four of the balloting for future products within this class.

10) Results of the Balloting

A. The P&T Committee voted unanimously to accept the amended recommendation that at least one brand Triptan be recommended for preferred status including different dosage forms. Medicaid should accept cost proposals so that at least one brand is selected as a preferred agent.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

B. The P&T Committee voted unanimously to accept the recommendation that no brand estrogens single entity is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

C. The P&T Committee voted to accept the recommendation that no brand estrogens combination products are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

D. The P&T Committee voted unanimously to accept the recommendation that no brand anti-inflammatory intranasal corticosteroid is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — [ ] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

E. The P&T Committee voted to accept the recommendation Nasalide possesses an extensive adverse effect profile or is clinically inferior to the other brand, generics and OTC products. Nasalide should not be given preferred status regardless of cost.

Medical Director — [✓] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

F. The P&T Committee voted unanimously to accept the recommendation that Atrovent is recommended for preferred status. Medicaid should accept Atrovent for preferred status.

Medical Director — [✓] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

G. The P&T Committee voted unanimously to accept the amended recommendation that at least one brand respiratory inhaled product, adrenals inhaled corticosteroid be recommended for preferred status. Medicaid should accept cost proposals so that at least one brand is selected as a preferred agent.

Medical Director — [✓] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

Commissioner — [✓] Approve [ ] Deny [ ] Approve with modification

H. The P&T Committee voted unanimously to accept the recommendation that no brand respiratory smooth muscle relaxants single entity is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — [x] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

I. The P&T Committee voted unanimously to accept the recommendation that no brand respiratory smooth muscle relaxants combination products are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — [x] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

J. The P&T Committee voted to accept the recommendation that Medicaid should work with manufacturers of the recommended brands of sympathomimetic single entity agents, Foradil and Serevent, on cost proposals so that at least one of the recommended brands is selected as a preferred agent. Medicaid should accept cost proposals from manufacturers to determine cost effective products so that as least one of the recommended products is placed in preferred status.

Medical Director — [x] Approve [ ] Deny [ ] Approve with modification

Deputy Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

Commissioner — [x] Approve [ ] Deny [ ] Approve with modification

K. The P&T Committee voted unanimously to accept the recommendation that no brand sympathomimetic combination products are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

L. The P&T Committee voted unanimously to accept the recommendation that no brand leukotriene modifiers are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

M. The P&T Committee voted unanimously to accept the recommendation that no brand mast cell stabilizers are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

N. The P&T Committee voted unanimously to accept the recommendation that no brand anti-arrhythmic agents are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

O. The P&T Committee voted unanimously to accept the recommendation that no brand carditonic agents are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

P. The P&T Committee voted unanimously to accept the recommendation that no brand nitrates and nitrites are recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification

(11) New Business: John Searey commented on the recent warning by the FDA surrounding the use of SSRIs. The Agency has asked that Heritage Information Systems, Inc. prepare a summary on the issues and present at the next Pharmacy and Therapeutics Committee meeting.

(12) Louise Jones stated that the next Pharmacy and Therapeutics Committee meeting will be May 26, 2004.

(13) Meeting was adjourned at 2:45 p.m.

Respectfully submitted.

Robert Berringer Date